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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/800,137  | 03/11/2004  | Lawrence Greenfield  | 07414.0022-02000    | 6944             |
| 22852   | 7590        | 08/09/2006           | EXAMINER            |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>901 NEW YORK AVENUE, NW<br>WASHINGTON, DC 20001-4413 |             |                      | RILEY, JEZIA        |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1637                |                  |

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/800,137

Applicant(s)

GREENFIELD ET AL.

Examiner

Jezia Riley

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-79, 82, 84, 90, 93-102, 108, 111-117, 119, 120 and 122 is/are rejected.
- 7) ☒ Claim(s) 80, 81, 83, 85-89, 91, 92, 103-107, 109, 110, 118, 121 and 123-126 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/14/05, 7/17/05, 3/14/06, 5/11/05, 9/20/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71, 72, 99, 100, 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 71, 72, 99, 100, 112 are vague and indefinite because they depend from a canceled claim.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 65-79, 82, 84, 90, 93-102, 108, 111-117, 119, 120, 122 are rejected under 35 U.S.C. 102(e) as being anticipated by Lienau et al. (6,548,256).

Lienau discloses a method and kit for isolating nucleic acids from a nucleic acid containing starting material, where the nucleic acids are released from the starting material and precipitated onto a trapping membrane. The method and kit may be used in the context of isolating genomic DNA or RNA from blood and isolating BACs from transformed bacterial cultures. The method includes mixing the starting material with a lysing and denaturing substance for release of the nucleic acid from the starting material. The lysing and denaturing substance of the invention causes the release of the nucleic acids from the intact cells of the starting material. The pH of the mixture is in the range of 7 to 8.5 and preferably in the range of 7.9 to 8.1. Typically, the lysing and denaturing substance includes a buffering agent, a salt NaCl, NaOAc, KOAc, NH<sub>4</sub>Cl, and the like, or mixtures), a detergent and a protease. The detergent is a quaternary amine cationic detergent, for example, cetyltrimethylammonium bromide (CTAB), and the like, and mixtures thereof, and the protease is Proteinase K. Example I describes the method which comprises: treatment of a blood sample with Proteinase K, cetyltrimethylammonium bromide, polyvinylpyrrolidone and Tris-HCL, pH 8 in a microfuge tube. Blood samples were obtained and preserved with heparin, sodium citrate and EDTA. Further alcohol and detergent substance, (70% isopropanol and 30%

Tween 20) was added to the supernatant and the sample was vortexed for 5 seconds. The method of Example I further comprises adding the sample to a microcentrifuge tube containing a trapping membrane which is viewed to be inclusive of the solid support. Further a resuspension buffer, (10 mM Tris-HCL, pH 8) was incubated on the membrane for 3 minutes at 70 degree. C.

5. Claims 80, 81, 83, 85-89, 91, 92, 103-107, 109, 110, 118, 121, 123-126 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thursday, July 13, 2006



JEZIA RILEY  
PRIMARY EXAMINER